Submitted Electronically

September 9, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: CMS-1807-P / Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure:

On behalf of our more than 5,400 nonprofit and mission-driven aging services providers from across the continuum of aging services, including home health and hospice, and our 36 state partners in 41 states, LeadingAge is pleased to offer the following comments in response to the proposed rule concerning CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies.

Section II.D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

LeadingAge supports the proposal in Section II.D.1.b(10) to add Caregiver Training Services (CTS), as described by HCPCS codes 97550 (caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living (ADLs), instrumental ADLs (iADLs), transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; initial 30 minutes) and CPT code 97551 (caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., ADLs, iADLs, transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; each additional 15 minutes (list separately in addition to code for primary service)) to the Medicare Telehealth List with provisional status for CY 2025, in addition to the other currently payable caregiver training service codes (CPT codes 97550, 97551, 97552, 96202, 96203).

We strongly supported the addition of these codes when CMS proposed doing so in the CY 2024 Physician Fee Schedule final rule, and we urged CMS at that time to add these codes to the Medicare Telehealth Services List.

We did so because the majority of family caregivers work either full-time or part-time, with nearly half working in hourly wage positions.[1] Many family caregivers miss work in order to accompany their loved ones to doctors' visits or support them during hospitalization, which has a significant impact on the caregiver themselves. Additionally, nearly 11 percent of caregivers live up to a mile away if not further

[1] AARP, and National Alliance for Caregiving. Caregiving in the U.S. AARP (Washington, DC: 2020).

from the patient, making it more difficult to join conversations for care planning purposes and receiving necessary education. For these reasons, and since the patient is not required to be present, these codes are a good fit for telehealth, will provide more flexibility to working caregivers as well as caregivers who do not live close to their loved ones and their care networks, and will support a variety of needs experienced by the individuals being supported by family caregivers.[2]

Understanding that these codes were first added to the PFS beginning in 2024, we support adding these services on a provisional basis to allow additional time for the development of evidence of clinical benefit when these services are furnished via telehealth for CMS to consider when evaluating these services for potential permanent addition to the Medicare Telehealth Services List.

For the same reasons, we also support the proposal that codes GCTD1-3 and GCTB1-2 be added to the Medicare Telehealth Services list for CY 2025 on a provisional basis, contingent upon finalizing the service code descriptions that CMS describes in section II.E. of this proposed rule.

LeadingAge also supports the proposal in Section II.D.1.d to remove through 2025 the frequency limitations for certain inpatient visits, nursing facility visits, and critical care consultation services. We supported the extension through 2024, and an additional extension will support access to care and provide CMS with an additional year of data to determine how practice patterns are evolving and what changes, if any, to frequency limitations should be made.

Due to the continued workforce shortage our members are experiencing, as are many healthcare practitioners with which our members partner or coordinate in delivery of care, we also support the proposal in Section II.D.2 of the proposed rule to extend the definition of direct supervision to permit virtual presence through December 31, 2025. Allowing physicians and other approved practitioners to virtually supervise telehealth visits allows for better coordination between teams and provides more flexibility to beneficiaries in scheduling virtual visits with their care team.

II.E. Payment for Caregiver Training Services

LeadingAge supports the proposal in Section II.E.4(39) to establish the following new coding and payment opportunities in support of caregivers.

- **Direct Care Caregiver Training Services**
  - GCTD1 (Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; initial 30 minutes)
  - GCTD2 (Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTD2 in conjunction with GCTD1)), and
  - GCTD3 (Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not

[2] An August 2024 National Health Statistics Report, for example (https://www.cdc.gov/nchs/data/nhsr/nhsr208.pdf#xd_co_f=OTY3OGI5ZDgtMDg5NS00ZmFmLTgyNGItMDdiNjM0ZmVkYzZl~), notes that users of post-acute and long-term care services in the U.S. experience difficulties with activities of daily living, including bathing and eating.

limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face with multiple sets of caregivers)).

- **Individual Behavior Management/Modification Caregiver Training Services**
  - GCTB1 (Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; initial 30 minutes) and
  - GCTB2 (Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTB2 in conjunction with GCTB1)).

Creation of these codes appropriately reflects that informal, unpaid caregivers are critical members of the interdisciplinary team for older adults and play an increasingly important role in supporting older adults who choose to age at home.

In addition to reducing complications related to ongoing conditions or illnesses, we also believe CMS has opportunities to support caregivers who are providing functional assistance that serves to prevent further deterioration, or adverse events like falls, and we encourage CMS to explore those needs and opportunities further.

For the reasons noted earlier in this letter concerning the realities of family caregiving, we also support the proposal to add these codes to the Medicare Telehealth Services List to accommodate a scenario in which the practitioner completes the caregiver training service via telehealth.

Recognizing the value of the interdisciplinary team, including family caregivers, we also encourage CMS to expand the CTS codes to include delegation of training by non-billing staff including nurses, certified nurse assistants, home health aides, medical assistants, and community health workers, under the supervision of a billing practitioner. Adding the ability of physicians and other approved practitioners to delegate, as appropriate, but still bill for CTS would be useful to practitioners and provide greater accessibility and flexibility to family caregivers. Physician and other approved providers are consistently stretched to their limit and rely extensively on their extended teams to provide support to patients and families currently.

We further note that, unfortunately, under current home health billing, social workers are not able to provide family caregiver training. And while a physician or other billing clinician could very well provide this training to under CTS coding, a social worker would also be an extremely valuable part of this service to help family caregivers understand how to understand and implement non-pharmacological interventions for loved ones with ADRD. We respectfully refer to LeadingAge's comments on the CY2025 Home Health Proposed Rule, in which we asked CMS to expand home health caregiver training codes to include social workers.[3]

Request for Information on Services Addressing Health-Related Social Needs

The CY 2025 proposed rule includes a broad request for information (RFI) on the newly implemented Community Health Integration (CHI) (HPCCS codes G0019, G0022), Principal Illness Navigation (PIN) (HCPCS codes G0023, G0024), Principal Illness Navigation—Peer Support (PIN-PS) (HCPCS codes G0140,

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[3] https://leadingage.org/wp-content/uploads/2024/08/LeadingAge-Comment-Letter-CY2025-HHA-Proposed-Rule-FINAL-8.26.24.pdf

G0146), and Social Determinants of Health Risk Assessment (SDOH RA) (HCPCS code G0136) services to engage interested parties on additional policy refinements for CMS to consider in future rulemaking.

CMS is interested in better addressing the social needs of beneficiaries and requesting information on the codes we created and finalized beginning in CY 2024 to fully encompass what interested parties and commenters believe should be included in the coding and payment we recently established.

LeadingAge applauded CMS for proposing the creation of new billing codes for community health integration (CHI), social determinants of health (SDOH) risk assessment, and principal illness navigation (PIN) services, which create pathways to sustain the essential contribution community-based efforts to address health related social needs as part of implementing a whole person model of care. This is critical in the care of older adults and something LeadingAge members work to achieve throughout the continuum of care.

We offered comments on the CY 2024 proposal and briefly reiterate certain of those comments here in response to the RFI, as perspective on opportunities to further fulfill the promise of these codes.

1) Concerning qualification for CHI and PIN services, our understanding is that the same practitioner that conducts the initiating visit must furnish and bill for both the CHI/PIN initiating visit and the CHI/PIN services. However, in many health care settings, physicians, APRNs, physician assistants, therapists, and others operate as care teams. This is particularly true in health professional shortage areas (HPSAs) where the beneficiary may be seen by more than one provider in a group practice, but each provider adheres to a shared care plan within the group practice or provider organization. We ask CMS to recognize the reality of practice today and honor the policy recognizing that within a group practice, there may be more than one provider conducting the initiating visit and engaging in subsequent general supervision delivery of CHI/PIN services and PIN services.

2) We further understand that CHI services provided to an individual cannot be billed while the patient is under a home health plan of care under Medicare Part B. In the CY2024 proposed rule, CMS noted that it believed there would be significant overlap between CHI and services furnished under a home health plan of care, particularly in relation to medical social services and comprehensive care coordination. We disagree with this assumption and encourage CMS to allow for concurrent CHI Services while the patient is under a home health plan of care under Medicare Part B. Because many CHI services would address complex needs, they often require multiple interventions over time. During the time that CHI services are being provided, the beneficiary may require home health services such physical therapy. We believe that not allowing concurrent provision of CHI services and home health plan of care could cause a disruption in the continuity of care for addressing health related social needs because the social service component is very limited during home health services, which are generally only sixty (60) days in duration. In addition, this would place the beneficiary in a position to have to choose between receiving services addressing multiple complex needs–for example housing assistance/services versus ongoing physical therapy–because it is extremely unlikely that the social service component of a limited-duration home health benefit would provide continuous social care interventions initiated by auxiliary personnel at the Medicare provider practice.

3) LeadingAge has many members that serve as community-based organizations (CBO) including a growing contingency of adult day programs, which could be exceptional partners in these programs. To assist CBOs with evaluating and seeking opportunities for partnership, we request that CMS continue to provide additional detail, clarification and guidance regarding:

- What arrangement would be needed to involve non-profit, community-based organizations, including to show sufficiency of clinical integration?

- Who bills Medicare for the service and how would the contracted CBO/CHWs be paid? Would they be paid separately by Medicare, or would the billing practitioner pay them?

PINs and Palliative Care: Our members that deliver palliative care were excited to see the principal illness navigation services proposal for 2024, knowing the need for these services for those with serious illness. However, adding PINs to the existing suite of care management services is not sufficient to make palliative care in the community sustainable under Part B – which is much needed. LeadingAge asks that CMS work to improve access to Part B palliative care through assigning adequate payment to an existing CMS comprehensive management and care coordination methodology. This structure could also be used for palliative care services across the continuum as well as a response to live discharge from hospice, with hospice teams focused on providing continuity of care for people with conditions that cause them to intermittently graduate from and return to hospice eligibility. LeadingAge recommends CMS assign a payment rate to CPT code S0311 and to CPT/Revenue Code S0311/069x combination for all Medicare beneficiaries. CMS should also assign covered services to be associated with S0311 to ensure consistency.

II.H. Supervision of Outpatient Therapy Services in Private Practices

LeadingAge supports the proposed change in policy to allow general supervision of occupational therapy assistants and physical therapy assistants for providers of Medicare Part B outpatient therapy services in private practice settings. This would align with supervision requirements in other settings, as well as current standards under state law, and would support beneficiaries access to care.

III.G. Medicare Shared Savings Program

Comments on CMS Proposals

Pre-Paid Shared Savings Distribution/Allocation. We support the proposal to expand access to pre-paid shared savings to existing ACOs. We believe this is an important tool, especially for smaller ACOs that may not have the same access to capital for ACO investments. This approach provides critical earlier access to funding to invest in needed infrastructure, staffing or beneficiary services and supports more quickly instead of waiting until months later. This allows an ACO to be more responsive to beneficiary needs and presents an opportunity to more successfully manage the beneficiary's needs.

We are intrigued by the new approach to require that at least 50% of these shared savings be reserved for spending on non-traditional Medicare services for beneficiaries such as meals, dental, vision, etc., akin to the Medicare Advantage program requiring rebate dollars to be used for these purposes. We note that you define what types of staffing the shared savings may be used for, and we believe that adding "or other direct care staff" might be beneficial. This would permit an ACO to deploy more home health, home care or hospice workers, or perhaps assist with increasing staffing at a particular site of service like a nursing home by helping to fund more certified nursing assistants or medication assistants or maybe an onsite dietitian. The current definition as proposed would not permit this approach.

We are pleased to see continued support for coordination with community-based services as part of the ACO model and that Medicare beneficiaries would have a new choice for accessing some non-traditional Medicare services through an ACO and not only a Medicare Advantage (MA) or Special Needs Plan (SNP). By adopting these expectations for how some portion of shared savings will be spent, it begins to offer Medicare beneficiaries a comparable option with what is currently available through supplemental benefits under MA/SNP to receive these non-traditional services. For this reason, we would suggest CMS consider applying this same approach to all ACO shared savings not just those that are prepaid so that these options are available to a broader group of beneficiaries.

Finally, we have recently raised the issue with CMS that the offering of some of these non-traditional Medicare benefits (e.g. flexible benefit cards used to pay for groceries, utilities and sometimes rent) by MA/SNP plans is now beginning to jeopardize some beneficiaries' eligibility for other government assistance programs. As CMS moves forward to apply similar expectations in the ACO environment, we ask for to also consider how to prevent these beneficiary services from negatively impacting beneficiaries' other government assistance programs.

Health Equity Benchmark Adjustment. Many LeadingAge members provide care and services to individuals in underserved communities and dual eligible beneficiaries. We also know the many challenges these populations face that can directly impact their health outcomes (e.g. stable housing, nutrition, etc.). MedPAC has noted the obstacles imposed within value-based programs for providers who serve these populations in achieving the desired outcomes. Therefore, we are in support of the effort to incentivize ACOs through a health equity benchmark adjustment to continue to serve these populations in recognition of these additional challenges.

Future Considerations for MSSP

If ACOs are going to be one of the primary accountable care models in traditional Medicare, then we must begin to consider how these ACOs engage non-physician providers in the care of older adults. Some Medicare beneficiaries reside in the community in single family homes and apartments, while others require more assistance with their activities of daily living and chronic condition management. This high-needs population often receives the bulk of their care from nursing staff and aides in residential settings such as long-stay nursing homes and assisted living. Therefore, we think CMS should continue to refine MSSP and other similar accountable care models in the following ways.

Pursue statutory change to permit other provider types to be the accountable entity and coordinator of care in an ACO. Under the current statutory limitations of the Medicare Shared Savings Program (MSSP), primary care physicians, hospitals and health systems are the only permitted leaders of this model. While primary care and specialty care physicians play an integral part in a Medicare beneficiaries care, we think the MSSP law should be revisited to permit a broader array of providers to be accountable for the total cost of beneficiaries' care as leaders of these models, similar to what is permitted under the ACO REACH program. Nursing homes often provide both post-acute care (skilled, short-stay), and long-stay custodial care where the nursing home is the beneficiary's residence. Long-stay nursing home residents are also Medicare beneficiaries even though the bulk of their care is funded through other payor sources. We encourage CMS to explore a residential-based ACO model where the nursing home is at risk for total cost of care and coordination with physicians, hospitals, health systems and other providers. CMS has yet to test such a residential-based hub of accountable care. We believe that economies of scale could be achieved through such an approach especially where the hub of care is where the person resides. In these cases, the individual beneficiary often has daily interaction with their care providers instead of a 20-minute office visit. Assisted living and other senior living communities should be considered for this model in addition to nursing homes. Hospice providers are also engaging in MSSP through the formation of physician practices but are essentially using their core skillsets to manage serious illness – forming a new entity to do so should not be a requirement for entry into the accountable care space.

Develop value-based arrangements that are embedded within the ACO for non-physician participating providers or organizations. (e.g. nursing homes, assisted living, home care, etc.) As the ACO model expands to more beneficiaries, we believe it is critical for the model to evolve and engage other providers in the work for managing total cost of care and improving outcomes. Most importantly, every provider who is involved in this work should share in the financial rewards of those labors. Accountable

care is a team sport and as such, there is less success when all providers involved in a beneficiary's care don't work together. This means all team members must be accountable and appropriately rewarded for their actions. The ACO model as it stands lauds that it reduces Post-Acute Care (PAC) spend to generate its savings. However, another way to look at this is robbing one provider to pay another. It is unsustainable and may ultimately create access issues as the current financing model for these PAC providers is no longer sustainable. CMS could help ensure ACOs adopt more value-based arrangements with PAC and other providers by offering a menu of value-based payments embedded within the ACO such as a nested bundle for SNF, home health, or palliative care/serious illness management services. The GUIDE model is potentially a good precedent for this – though we have to see what the "nesting" looks like in the RFP.

Consider new avenues for beneficiary assignment to ACOs. As CMS seeks to improve beneficiary assignment, we encourage CMS to explore assigning Medicare beneficiaries who reside in nursing homes for long-stay custodial care (100 days or more). We understand that often residents of long-stay nursing homes may be enrolled in an ACO based on the plurality of the primary care received when they still resided in the community but now they receive this care via the nursing home and/or an affiliated physician practice. For this reason, the misaligned assignment holds an ACO accountable for a nursing home resident that they rarely if ever see and a nursing home with which they may not partner. For these reasons, we would encourage CMS to explore ways for the nursing home to participate in an ACO that would result in their residents being assigned to an ACO. One possible approach may be to allow nursing homes to exclusively align their tax identification number to a particular ACO and this would assign their Medicare FFS beneficiaries to the ACO. This may require CMS to establish an additional role for nursing homes where this could occur vs. SNF Affiliate roles or preferred providers.

By creating a role for nursing homes and possibly other aging service providers in beneficiary assignment, it also elevates their position within an ACO as a whole, including the possibility of having a seat at the decision-making table for distribution of shared savings and care delivery redesign. This engagement could lead to even greater success at managing Medicare beneficiaries who receive long-term services and supports within nursing homes and assisted living communities.

We cannot leave these providers out of the financial rewards of improving outcomes or these services/providers will cease to exist as their payments and units of services continue to be reduced by ACOs and Medicare Advantage plans. We are always available to discuss these and other options for meaningful participation for PAC and LTSS providers in the MSSP and other models.

III.O. Medicare Parts A and B Overpayment Provisions of the Affordable Care Act

In the December 2022 Overpayment Proposed Rule, CMS proposed to remove the existing "reasonable diligence" standard and adopt by reference the False Claims Act definition of "knowing" and "knowingly" as set forth at 31 U.S.C. 3729(b)(1)(A) but has not yet finalized those proposals. In this current proposed rule, CMS notes that it is retaining its prior proposals and is now making additional proposals to revise existing regulations at § 401.305(b) regarding the deadline for reporting and returning overpayments.

With respect to incorporating the False Claims Act definition, as was proposed in 2022, we ask CMS to provide additional clarification or guidance concerning what it means to be in "reckless disregard" or "deliberate ignorance" that a provider received or retained an overpayment.

In our comments on the proposed 2022 rule, we urged CMS to clarify that providers would continue to have a reasonable opportunity to determine the scope of an overpayment and quantify it, a process that commonly can take longer than 60 days to complete. We support the additional language CMS is now

proposing as § 401.305(b)(3) that would specify circumstances under which the deadline for reporting and returning overpayments would be suspended to allow time for providers to investigate and calculate overpayments. This addresses a concern that CMS had previously proposed to remove the term "quantified" from the original regulatory text.

CONCLUSION

We thank you for your consideration of the issues highlighted above. Please contact me (jlips@leadingage.org) if we can answer any questions or provide additional information.

Sincerely,

Jonathan Lips

Jonathan Lips, Vice President Legal Affairs

About LeadingAge*: We represent more than 5,400 nonprofit and mission-driven aging services providers and other organizations that touch millions of lives every day. Alongside our members and 36 partners in 41 states, we use applied research, advocacy, education, and community-building to make America a better place to grow old. Our membership encompasses the continuum of services for people as they age, including those with disabilities. We bring together the most inventive minds in the field to lead and innovate solutions that support older adults wherever they call home. For more information, visit leadingage.org.*